K050354 MAR 2 1 2005

510(k) Summary
for
Sirona Dental Systems
PerioScan

1. SPONSOR

Sirona Dental Systems GmbH
Farbrikstrasse 31
64625 Bensheim
Germany

Contact Person: Fritz Kolle
Regulatory Manager

Date Prepared: February 11, 2005

2. Device Name

Proprietary Name:	PerioScan Ultrasonic Scaler
Common/Usual Name:	Ultrasonic Scaler
Classification Name:	Ultrasonic Scaler

3. Predicate Devices

EMS Piezon Master 600 (K022328)

4. INTENDED USE

The Sirona PerioScan is an ultrasonic scaler intended for use in the following dental and periodontal applications:

- Removal of supragingival calculus
- Removal of subragingival calculus
- Periodontal therapy
- Preparing proximal cavities (micropreparation)
- Seating tooth-colored inlays and onlays with highly thixotropic dual curing cements

- Root canal irrigation
- Retrograde root canal treatment

5. DEVICE DESCRIPTION

The Sirona PerioScan Ultrasonic Scaler consists of a table-top unit with two detachable irrigant bottles with lids, a footswitch, an ultrasonic handpiece, hoses and connectors, a variety of optional tips for different dental procedures, and a tool for attaching the tips to the handpiece.

The PerioScan table-top houses the operator input and controls for the supply of irrigant, cooling liquid and light for the handpiece. The device is connected to 115V mains power supply and it may be connected to an external water-supply. The irrigant for the handpiece is drawn from either of the two internal liquid containers or an external water supply. The handpiece is connected to the table-top unit via a hose and can be deposited in the claw. A footswitch with two single switches controls the handpiece. The PerioScan Handpiece is an electrically operated scaler driven by a piezo oscillator. The handpiece includes an illumination LED located in the hose and a spray water controller.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The overall design of the Sirona PerioScan Ultrasonic Scaler is similar to the design of the Piezon® Master 600. Both these devices include a dental handpiece and ultrasonic generator. They all contain software, which controls delivery of the ultrasonic power, and include various tip configurations for the differing dental procedures.

On both the proposed and predicate Piezon 600 scaler units, the ultrasonic power can be adjusted on the control unit and delivery of the ultrasonic energy is via a foot control.

The Sirona PerioScan Scaler and the Piezon® Master 600 allow the operator to select among different operating modes. These modes have different ultrasonic power ranges to assist the operator in maintaining the ultrasonic power within an appropriate range for specific applications.

Both systems allow for irrigation using two internal containers (small and large) or an external water source. Irrigation flow is controlled by handpiece, operator's panel and footswitch for the Sirona PerioScan as well as for the Piezon® Master 600.

Based on the comparison of intended use and technical features, Sirona Dental Systems believes that the PerioScan is substantially equivalent to the Piezon® Master 600. The proposed and predicate devices have the same general intended use and principles of operation. The overall design of the proposed and predicate devices is similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 1 2005

Sirona Dental Systems GmbH
C/O Ms. Mary McNamara-Cullinane
Staff Consultant
Medical Devices Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760-4153

Re: K050354
Trade/Device Name: PerioScan Ultrasonic Scaler
Regulation Number: 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: February 11, 2005
Received: February 14, 2005

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

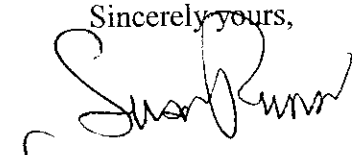
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050354

Device Name: PerioScan Ultrasonic Scaler

Indications for Use:

The Sirona Dental Systems PerioScan Ultrasonic Scaler is an ultrasonic scaler intended for use in the following dental and periodontal applications:

- Removal of supragingival and subgingival calculus
- Periodontal therapy
- Preparing proximal cavities (micropreparation)
- Seating tooth-colored inlays and onlays with highly thixotropic dual curing cements
- Root canal irrigation
- Retrograde root canal treatment

Prescription Use ___X___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Div. Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K050354